Exactech®

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GAINESVILLE, FL 32653

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K002141

AUG 16 2000

# Exactech® AcuMatch™ Integrated Hip System Press-Fit Femoral Components

## 510(k) Summary of Safety and Effectiveness Special 510(k)

Sponsor: Exactech® Inc.
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FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
V.P. of Research and Development

Date: July 14, 2000

# Exactech® AcuMatch™ Integrated Hip System
# Press-Fit Femoral Components

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

**Classifications / Proprietary Names:**

| | |
|---|---|
| Classification Name: | Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (Femoral Component) |
| Trade / Proprietary Model Names: | ***AcuMatch P-Series Press-Fit Plasma***<br>***AcuMatch P-Series Press-Fit***<br>***AcuMatch L-Series Press-Fit*** |
| Product Code: | LWJ |
| C.F.R. Section: | not specified |
| Device Class: | II |
| Classification Panel: | Orthopedic |

| | |
|---|---|
| Classification Name: | Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate (Femoral Component) |
| Trade / Proprietary Model Names: | ***AcuMatch P-Series Press-Fit Plasma / HA***<br>***AcuMatch P-Series Press-Fit / HA***<br>***AcuMatch L-Series Press-Fit / HA*** |
| Product Code: | MEH |
| C.F.R. Section: | not specified |
| Device Class: | II |
| Classification Panel: | Orthopedic |

# Exactech® AcuMatch™ Integrated Hip System
# Press-Fit Femoral Components

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

**Legally Marketed Devices for Substantial Equivalence Comparison:**

The Exactech AcuMatch Press-Fit Stems are made of similar materials and are of a similar design to other legally marketed femoral components, most notably the Exactech MCS femoral components:

| Model | Manufacturer | 510(k) Number | Product Code |
|---|---|---|---|
| MCS | Exactech | 921113 | LPH |
| MCS/HA | Exactech | 990197 | MEH |
| Perfecta | Wright Medical Technology | ---------- | ---------- |
| Synergy HA | Smith & Nephew | ---------- | ---------- |
| Synergy Press-Fit | Smith & Nephew | ---------- | ---------- |
| Secur-Fit HA | Osteonics | ---------- | ---------- |
| APR Fully Textured | Sulzer | ---------- | ---------- |

**Device Description**

*Indications for Use:*

AcuMatch Press-Fit Stems are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of AcuMatch Integrated Hip Systems are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

# Exactech® AcuMatch™ Integrated Hip System
# Press-Fit Femoral Components

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

AcuMatch Press-Fit Femoral Components are intended to be used in press-fit applications. Components without the hydroxyapatite (HA) coating may also be used with bone cement.

*Contraindications:*

AcuMatch Press-Fit Femoral Components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

The indications/contraindications for use for the proposed AcuMatch Press-Fit Femoral Components are identical to those of our predicate Exactech MCS and MCS/HA Femoral Components (#K921113,#K990197).

*Packaging Materials:*

| Material | Composition |
|---|---|
| Inner / Outer Trays | PETG – 0.040" thickness |
| Tray Lids | Spun-Bonded Olefin - Tyvek® |
| Inserts | Medium grade LD45 Foam |
| Box | Heavy weight cardboard |
| Outer Shrink-Wrap | Clear, Light-Weight Plastic |
| Shipping Cartons | Heavy-weight Corrugated Cardboard |

Utilization and implantation instructions are included in the package insert provided with each product. The name, size, dimension, material, lot, serial number and sterility status are indicated on the labeling.

*Sterilization Specifications:*

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): $10^{-6}$

# Exactech® AcuMatch™ Integrated Hip System
# Press-Fit Femoral Components

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

*Substantial Equivalency Comparison:*

Like the Exactech MCS models (ref. #K921113 and #K990197), the proposed AcuMatch models are composed of titanium alloy (Ti-6Al-4V), have a trapezoidal cross-sectional geometry, secondary distal tapers, optional calcar collars and optional hydroxyapatite (HA) coatings. The HA coating available on the AcuMatch models is identical to the one used for the predicate MCS component.

The differences in design features between the proposed AcuMatch and predicate MCS models include changes in the manufacturing technique, dimensional modifications to the neck region, a new sizing differential and changes to the surface presentations.

These design changes for the proposed AcuMatch models do not affect the intended use of the device and do not alter the fundamental scientific technology of the device.

In addition, the AcuMatch Press-Fit Stems have basic design features in common with femoral components designed by other orthopedic companies. These include but are not limited to Wright Medical's "Perfecta", Osteonic's "Secur-Fit HA", Sulzer's "APR Fully Textured" and Smith & Nephew's "Synergy" press-fit designs.

*Performance Information:*

Functional tests were conducted to verify that the performance of the AcuMatch Press-Fit stems would be adequate for anticipated *in vivo* loading. This performance data included fatigue testing of production quality parts, rotating beam fatigue tests of the wrought and forged materials, and vendor material certifications. The AcuMatch results exceeded those of the predicate MCS design which has a clinical history in excess of 7 years with no reported stem failures.

Based on the fatigue performance data, material specifications and design considerations, it is felt that the Exactech AcuMatch Press-Fit femoral components are substantially equivalent to the Exactech MCS femoral components (#K921113, #K990197).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2000

Ms. Lisa Simpson
Regulatory Representative
Exactech
2320 NW 66th Court
Gainesville, Florida 32653

Re: K002141
Trade Name: AcuMatch P-Series Press-Fit, Plasma and HA Coated Femoral Components AcuMatch L-Series Press-Fit and HA Coated Femoral Components
Regulatory Class: II
Product Code: LWJ and MEH
Dated: July 14, 2000
Received: July 17,2000

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Exactech® AcuMatch™ Integrated Hip System
# Press-Fit Femoral Components

## Indications for Use

**510(k) Number:** K002141

**Device Name:** AcuMatch P-Series Press-Fit Plasma
AcuMatch P-Series Press-Fit
AcuMatch L-Series Press-Fit

AcuMatch P-Series Press-Fit Plasma/HA
AcuMatch P-Series Press-Fit/HA
AcuMatch L-Series Press-Fit/HA

**Intended Use / Indications:**

AcuMatch Press-Fit Femoral Components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of the AcuMatch Integrated Hip System are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

AcuMatch Press-Fit Femoral Components are intended to be used in press fit applications. Components without the optional hydroxyapatite (HA) coating may also be used in cemented applications.

**Contraindications:**

AcuMatch Press-Fit Femoral Stem Components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE) Donna-Bea Tillman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002141

Prescription Use Yes or Over the Counter Use No